



BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2018-0560; FRL-10002-21]

#### Fenhexamid; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of fenhexamid in or on multiple commodities identified and discussed later in this document. Interregional Research Project No. 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the SUPPLEMENTARY INFORMATION).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2018-0560, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202)

566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this action apply to me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

*B. How can I get electronic access to other related information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl)

*C. How can I file an objection or hearing request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2018-0560 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2018-0560, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of

boxed information, please follow the instructions at

<http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

## **II. Summary of Petitioned-For Tolerance**

In the **Federal Register** of October 18, 2018 (83 FR 52787) (FRL-9984-21), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8E8689) by Interregional Research Project Number 4 (IR-4) Rutgers, The State University of New Jersey, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.553 be amended by establishing tolerances for residues of the fungicide fenhexamid, (N-2,3-dichloro-4-hydroxyphenyl)-1-methylcyclohexanecarboxamide), in or on arugula at 30.0 parts per million (ppm); berry, low growing, subgroup 13-07G at 3.0 ppm; bushberry subgroup 13-07B at 5.0 ppm; caneberry subgroup 13-07A at 20.0 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 4.0 ppm; fruit, stone, group 12-12, except plum, prune, fresh, postharvest at 10.0 ppm; garden cress at 30.0 ppm; kiwifruit, fuzzy at 30.0 ppm; leafy greens, subgroup 4-16A, except spinach at 30.0 ppm; onion, bulb, crop subgroup 3-07A at 2.0 ppm; onion, green, subgroup 3-07B at 30.0 ppm; upland cress at 30.0 ppm; vegetable, fruiting, group 8-10, except non-bell pepper at 2.0 ppm. Also, the petition requested to remove existing tolerances in 40 CFR 180.553 for residues of the fungicide fenhexamid in or on the raw agricultural commodities: Bushberry subgroup 13B at 5.0 ppm; caneberry subgroup 13A at 20.0 ppm; cilantro, leaves at 30.0 ppm; fruit, stone, group 12, except plum, prune, fresh, postharvest at 10.0

ppm; grape at 4.0 ppm; juneberry at 5.0 ppm; kiwifruit, postharvest at 15.0 ppm; leafy greens subgroup 4A, except spinach at 30.0 ppm; lingonberry at 5.0 ppm; salal at 5.0 ppm; strawberry at 3.0 ppm; and vegetable, fruiting, group 8, except nonbell pepper at 2.0 ppm. That document referenced a summary of the petition prepared by Arysta LifeSciences, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA is establishing tolerances at levels that vary from what the petitioner requested, in accordance with its authority under section 408(d)(4)(A)(i) of the FFDCA. The reasons for these changes are explained in Unit IV.C.

### **III. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in

FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for fenhexamid including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fenhexamid follows.

*A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Following repeated oral dosing, the most toxicologically relevant effects were hematological changes (decreased red blood cell (RBC) counts, hemoglobin, and hematocrit and increased Heinz bodies) in dogs, and decreased body weights, increased food consumption, and decreased liver and/or kidney weights in rats and mice. There is no evidence of immunotoxicity or neurotoxicity in the fenhexamid database. There is no evidence of qualitative or quantitative susceptibility in the developmental studies in rats and rabbits. In the reproductive study, decreased body weights in F1 and F2 pups were observed in the presence of maternal toxicity. However, there is no concern for increased susceptibility of offspring because a clear no-observed-adverse-effect-level (NOAEL) and a well-characterized dose response for offspring effects was observed in the presence of maternal toxicity. There were no adverse effects observed in a dermal toxicity study up to the highest dose tested (1,000 mg/kg/day). Although no subchronic inhalation study is

available for fenhexamid, a 5-day range finding inhalation study reported lung-specific effects (macroscopic grey coloration of the lungs and marginal increases in lung weights) at the highest dose tested. However, concern for these effects is low because they occurred at a dose more than 7X higher than the selected inhalation points of departure (POD). In an acute neurotoxicity study in rats, the only effect observed was a marginally decreased mean body temperature in male rats following a single high dose of 2,000 mg/kg. This effect is not considered to be biologically significant.

Based on the lack of evidence of carcinogenicity in rats and mice and on the lack of genotoxicity in an acceptable battery of mutagenicity studies, EPA has classified fenhexamid as “not likely” to be a human carcinogen. Specific information on the studies received and the nature of the adverse effects caused by fenhexamid as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document titled Fenhexamid: “Human Health Risk Assessment for Section 3 Registration for New Uses in/on Onion Bulb Subgroup 3-07A; Onion Green Subgroup 3-07B; Fuzzy Kiwifruit; Crop Group Conversions/Expansions for Fruit Small Vine Climbing, except Fuzzy Kiwifruit Subgroup 13-07F; Berry Low Growing Subgroup 13-07G; Caneberry Subgroup 13-07A; Bushberry Subgroup 13-07B; Fruit Stone Group 12-12, except Plum, Prune Fresh; Leafy Greens Subgroup 4-16A except Spinach; Vegetable Fruiting Group 8-10 except Non bell Pepper; and to Establish Individual Tolerances on Arugula; Garden cress; Upland Cress” at page 27 in docket ID number EPA-HQ-OPP-2018-0560.

*B. Toxicological Points of Departure/Levels of Concern*

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides>.

A summary of the toxicological endpoints for fenhexamid used for human risk assessment is shown in Table 1 of this unit.

Table 1. -- Summary of Toxicological Doses and Endpoints for fenhexamid for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (General population)	Not selected. No appropriate toxicological endpoint attributable to a single exposure was identified in the available toxicology studies.		



including infants and children)			
Chronic dietary (All populations)	NOAEL= 17 mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Chronic RfD = 0.17 mg/kg/day  cPAD = 0.17 mg/kg/day	1-year feeding study (dog) LOAEL = 124 mg/kg/day based on decreased RBC counts, hemoglobin, and hematocrit and increased Heinz bodies in males and females; increased adrenal weights and intracytoplasmic vacuoles in adrenal cortex in females.
Cancer (Oral)	Classification: “Not likely to be Carcinogenic to Humans” based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day= milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF<sub>A</sub> = extrapolation from animal to human (interspecies). UF<sub>H</sub> = potential variation in sensitivity among members of the human population (intraspecies).

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to fenhexamid, EPA considered exposure under the petitioned-for tolerances as well as all existing fenhexamid tolerances in 40 CFR 180.553. EPA assessed dietary exposures from fenhexamid in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for fenhexamid; therefore, a quantitative acute

dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID) Version 3.16. This software uses 2003-2008 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA conducted an unrefined chronic dietary exposure assessment using tolerance-level residues, 100 percent crop treated (100 PCT), and HED's 2018 default processing factors.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that fenhexamid does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for fenhexamid. Tolerance-level residues and/or 100% CT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for fenhexamid in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fenhexamid. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide>.

Based on the Pesticides in Water Calculator (PWC version 1.52; Feb. 2016)

model, the estimated drinking water concentrations (EDWCs) of fenhexamid for chronic exposures for non-cancer assessments, EDWCs of fenhexamid are estimated to be 144 ppb for surface water and 1986 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 1986 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Fenhexamid is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common method of toxicity, EPA has not made a common mechanism of toxicity finding as to fenhexamid and any other substances and fenhexamid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that fenhexamid has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the

cumulative effects of such chemicals, see EPA's website at

<http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>.

#### *D. Safety Factor for Infants and Children*

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There is no evidence of qualitative or quantitative susceptibility in the developmental studies in rats and rabbits. In the reproductive study, decreased body weights in F1 and F2 pups were observed in the presence of maternal toxicity. However, there is no concern for increased susceptibility of offspring because a clear no-observed-adverse-effect-level (NOAEL) and a well-characterized dose response for offspring effects was observed in the presence of maternal toxicity.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for fenhexamid is complete.

ii. There is no indication that fenhexamid is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that fenhexamid results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies and no concern for any increased susceptibility in the young from the 2-generation reproduction study due to the clear dose-response and NOAEL of that study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fenhexamid in drinking water. These assessments will not underestimate the exposure and risks posed by fenhexamid.

#### *E. Aggregate Risks and Determination of Safety*

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, fenhexamid is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fenhexamid from food and water will utilize 79% of the cPAD for all infants (<1 year old), the population subgroup receiving the greatest exposure. There are no residential uses for fenhexamid. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of fenhexamid is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

A short-term adverse effect was identified; however, fenhexamid is not registered for any use patterns that would result in short-term residential exposure. Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure. Because there is no short-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for fenhexamid.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

An intermediate-term adverse effect was identified; however, fenhexamid is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus

chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for fenhexamid.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, fenhexamid is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to fenhexamid residues.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

Adequate enforcement methodology Bayer AG Method 00362, a high-performance liquid chromatography (HPLC) method with electrochemical detection (ECD) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

##### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs)

established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

Codex MRLs for head and leaf lettuce; eggplant, tomato, and bell pepper; and apricot, nectarine, and peach are harmonized with the U.S. tolerances for fenhexamid on leafy greens subgroup 4-16A, except spinach; vegetable, fruiting, group 8-10, except non bell pepper; and fruit, stone, group 12-12, except plum, prune, dried, respectively. The Codex MRLs for other stone fruits in crop group 12-12 are lower than the crop group tolerance; harmonizing with them could result in over-tolerance residues in the U.S. despite legal use of the pesticide according to the label.

The established U.S. tolerances for fenhexamid in or on caneberry subgroup 13-07A and kiwifruit, fuzzy are 20 ppm and 30 ppm respectively. These values are higher than the Codex MRL values of 15 ppm for individual commodities in caneberry subgroup 13-07A and kiwifruit, fuzzy. The U.S. tolerance values for fenhexamid on caneberry subgroup 13-07A and kiwifruit, fuzzy were determined based on expected residues resulting from U.S. use pattern; harmonizing with Codex MRL values may result in over tolerance residues. The established U.S. tolerances for residues of fenhexamid in grape and strawberry are currently harmonized with Canada but are lower than the established Codex MRLs. These U.S. tolerances were established as part of a joint review with the



Health Canada Pest Management Regulatory Agency (PMRA); therefore, EPA is not raising these tolerances to harmonize with Codex.

### *C. Revisions to Petitioned-For Tolerances*

EPA has revised the proposed tolerances for residues of fenhexamid on onion bulb subgroup 3-07A; onion green subgroup 3-07B; fuzzy kiwifruit; fruit small vine climbing, except fuzzy kiwifruit subgroup 13-07F; berry low growing subgroup 13-07G; caneberry subgroup 13-07A; bushberry subgroup 13-07B; fruit stone group 12-12, except plum prune fresh; leafy greens subgroup 4-16A except spinach; vegetable fruiting group 8-10 except nonbell pepper; arugula; garden cress and upland cress based on current OECD rounding classes. In addition, EPA corrected the commodity definition for fruit, stone, group 12-12, except plum, prune, fresh and plum, prune, dried.

## **V. Conclusion**

Therefore, tolerances are established for residues of fenhexamid, in or on arugula at 30 ppm; berry, low growing, subgroup 13-07G at 3 ppm; bushberry subgroup 13-07B at 5 ppm; caneberry subgroup 13-07A at 20 ppm; cress, garden at 30 ppm; cress, upland at 30 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 4 ppm; fruit, stone, group 12-12, except plum, prune at 10 ppm; kiwifruit, fuzzy at 30 ppm; leafy greens, subgroup 4-16A, except spinach at 30 ppm; onion, bulb, subgroup 3-07A at 2 ppm; onion, green, subgroup 3-07B at 30 ppm; and vegetable, fruiting, group 8-10, except nonbell pepper at 2 ppm.

Additionally, the existing tolerances on the following commodities are removed as unnecessary due to the establishment of the above tolerances: bushberry subgroup 13B; caneberry subgroup 13A; cilantro, leaves; fruit, stone, group 12, except plum,

prune, fresh, postharvest; grape; junberry; kiwifruit, postharvest; leafy greens subgroup 4A, except spinach; lingonberry; salal; strawberry; and vegetable, fruiting, group 8, except nonbell pepper. Finally, EPA is revising the tolerance expression to be consistent with Agency policy.

## **VI. Statutory and Executive Order Reviews**

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5

U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the National Government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

## **VII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as

defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 6, 2019.

**Michael Goodis,**

*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. In § 180.553, amend paragraph (a) as follows:

- a. Revise the introductory text;
- b. Add alphabetically the entries for “Arugula” and “Berry, low growing, subgroup 13-07G”;
- c. Remove the entry for “Bushberry subgroup 13B”;
- d. Add alphabetically the entry for “Bushberry subgroup 13-07B”;
- e. Remove the entry for “Caneberry subgroup 13A”;
- f. Add alphabetically the entry for “Caneberry subgroup 13-07A”;
- g. Remove the entry for “Cilantro, leaves”;
- h. Add alphabetically the entries for “Cress, garden”; “Cress, upland”; “Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F”; and “Fruit, stone, group 12-12, except plum, prune”;
- i. Remove the entries for “Fruit, stone, group 12, except plum, prune, fresh, postharvest”; “Grape”; and “Juneberry”;
- j. Add alphabetically the entry for “Kiwifruit, fuzzy”;
- k. Remove the entries for “Kiwifruit, postharvest” and “Leafy greens subgroup 4A, except spinach”;
- l. Add alphabetically the entry for “Leafy greens, subgroup 4-16A, except spinach”;

- m. Remove the entry for “Lingonberry”;
- n. Add alphabetically the entries for “Onion, bulb, subgroup 3-07A” and “Onion, green, subgroup 3-07B”;
- o. Remove the entries for “Salal”; “Strawberry”; and “Vegetable, fruiting, group 8, except nonbell pepper”; and
- p. Add alphabetically the entry for “Vegetable, fruiting, group 8-10, except non bell pepper”.

The revisions and additions read as follows:

**§ 180.553 Fenhexamid; tolerances for residues.**

(a) *General.* Tolerances are established for residues of fenhexamid, including its metabolites and degradate, in or on the commodities in the table in this paragraph (a). Compliance with the tolerance levels specified in this paragraph (a) is to be determined by measuring only fenhexamid (*N*-2,3-dichloro-4-hydroxyphenyl)-1-methylcyclohexanecarboxamide).

Commodity	Parts per million
* * * * *	
Arugula	30
* * * * *	
Berry, low growing, subgroup 13-07G	3
Bushberry subgroup 13-07B	5
Caneberry subgroup 13-07A	20
Cress, garden	30
Cress, upland	30
* * * * *	
Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F	4
Fruit, stone, group 12-12, except plum, prune	10
* * * * *	
Kiwifruit, fuzzy	30
Leafy greens, subgroup 4-16A, except spinach	30
Onion, bulb, subgroup 3-07A	2
Onion, green, subgroup 3-07B	30
* * * * *	

Vegetable, fruiting, group 8-10, except nonbell pepper	2
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